**IN THE UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**
**NEWARK DIVISION**

| | | |
|---|---|---|
| **BILLYJOE CARROLL**<br><br>**Plaintiff,**<br><br>**v.**<br><br>**ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA LP.**<br><br>**Defendants.** | :<br>:<br>:<br>:<br>:<br>:<br>:<br>:<br>:<br>:<br>:<br>: | **Civil Action No.**<br><br>**COMPLAINT AND DEMAND FOR JURY TRIAL** |

# COMPLAINT

Plaintiff, BillyJoe Carroll, by way of Complaint against Defendants, AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively "Defendants) alleges as follows:

## NATURE OF THE ACTION

1. This is an action for personal injuries and economic damages suffered by Plaintiff, BillyJoe Carroll, as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling and/or sale of the proton pump inhibiting ("PPI") drug known as Nexium (esomeprazole magnesium) and/or other Nexium-branded products with the same active ingredient herein collectively referred to as "NEXIUM".

## PARTIES

2. At all times referenced herein, Plaintiff, BillyJoe Carroll, was and is a citizen of the State of Alabama.

AstraZeneca Pharmaceuticals LP

3. Defendant AstraZeneca Pharmaceuticals LP is, and all times relevant to this action was, a Delaware corporation with its corporate headquarters in Wilmington, Delaware.

4. At all times relevant hereto, Defendant AstraZeneca Pharmaceuticals LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Nexium products.

5. Upon information and belief, at all relevant times, Defendant AstraZeneca Pharmaceuticals LP was present and doing business in Plaintiff's state of residency and the State of New Jersey.

6. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP transacted, solicited and conducted business in Plaintiff's state of residency and the State of New Jersey and derived substantial revenue from such business.

7. At all relevant times, Defendant AstraZeneca Pharmaceuticals LP expected or should have expected that its acts would have consequences throughout the United States of America including the State of New Jersey in particular.

8. Defendant AstraZeneca Pharmaceuticals LP is the holder of approved New Drug Applications ("NDAs") for the following forms of Nexium: Delayed-Release Capsule Pellets (20 mg and 40 mg), with NDA #021153, approved on 2/20/2001; Delayed-Release Oral Suspension Packets (2.5MG, 5MG, 20MG, 40MG), with NDA # 021957, approved on 10/20/2006; Delayed-Release Oral Suspension Packets (10MG), with NDA # 022101, approved

on 02/27/2008; and Injection (20MG VIAL, 40MG VIAL), with NDA # 022101, approved on 03/31/2005.

AstraZeneca LP

9. At all relevant times, Defendant AstraZeneca LP was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Nexium products.

10. Defendant AstraZeneca LP is, and all times relevant to this action was, a Delaware Corporation with its corporate headquarters in Wilmington, Delaware.

11. Upon information and belief, at all relevant times, Defendant AstraZeneca LP was present and doing business in Plaintiff's state of residency and the State of New Jersey.

12. At all relevant times, Defendant AstraZeneca LP transacted, solicited and conducted business in Plaintiff's state of residency and the State of New Jersey and derived substantial revenue from such business.

13. At all relevant times, Defendant AstraZeneca LP expected or should have expected that its acts would have consequences throughout the United State of America, including the State of New Jersey in particular.

Defendants' Unity of Interest

14. Upon information and belief, at all relevant times, each of the Defendants and their directors and/or officers acted within the scope of their authority for and on behalf of the other Defendant. During all relevant times, Defendants possessed a unity of interest between themselves and exercised control over their respective subsidiaries and affiliates.

15. Upon information and belief, at all relevant times, each Defendant was the agent and employee of the other Defendant, and in performing the wrongful acts alleged, each Defendant was acting within the course and scope of such agency and employment with each

Defendants' actual and implied permission, consent, authorization and approval. As such, each Defendant is individually, as well as jointly and severally, liable to Plaintiffs for Plaintiff's injury, losses and damages.

16. Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP are thus collectively referred to herein as "Defendants" or "AstraZeneca".

## JURISIDCTION AND VENUE

17. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332(a)(1) because this case is a civil action where the matter in controversy exceeds $75,000, exclusive of interest and costs, and is between citizens of different States.

18. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) as a substantial part of the events and/or omissions giving rise to the Plaintiff's claims emanated from activities within this jurisdiction and Defendants transact substantial business within this jurisdiction.

19. Consistent with the Due Process Clause of the Fifth and Fourteenth Amendments, the Court has personal jurisdiction over Defendants, because Defendants are present in the State of New Jersey, such that the exercise of jurisdiction does not offend traditional notions of fair play and substantial justice.

20. This Court has personal jurisdiction over Defendants pursuant to and consistent with the Constitutional requirements of Due Process because Defendants, acting through their agents or apparent agents, committed one or more of the following: transaction of business within the state of New Jersey; making of contracts within the state; the commission of a tortious act within this state; and the ownership, use, or possession of any real estate situated within this state as well as registered as foreign partnerships to do business within the state and maintaining a registered agent for service of process.

21. Requiring Defendants to litigate these claims in New Jersey does not offend traditional notions of fair play and substantial justice and is permitted by the United States Constitution. All of Plaintiff's claims arise in part from conduct Defendants purposefully directed to the State of New Jersey. Upon information and belief, Defendants' Nexium products are sold at hundreds of local and national pharmacies, including, but not limited to Wal-Mart, Target, CVS, and Walgreens throughout the State of New Jersey.

22. Upon information and belief, Defendants avail themselves of numerous advertising and promotional materials regarding their defective Nexium products specifically intended to reach consumers in Plaintiff's home state and the State of New Jersey, including but not limited to advertisements on local television programs, advertisements on local radio broadcasts, advertisements on billboards and advertisements in print publications delivered to consumers in Plaintiff's home state of and the State of New Jersey.

23. Plaintiff's claims arise out of Defendants' design, marketing and/or sale of Nexium products in the State of New Jersey.

24. Defendants regularly conduct or solicit business and derive substantial revenue from goods used or consumed in, inter alia, the State of New Jersey.

25. At all relevant times, Defendants were present and doing business in the State of New Jersey.

26. At all times relevant hereto, Defendants transacted, solicited, and conducted business in the State of New Jersey and derived substantial revenue from such business.

27. At all relevant times, Defendants placed Nexium products ingested by Plaintiff into the stream of interstate commerce.

28. At all relevant times, Defendants expected or should have expected that their acts and omissions would have consequences within the United States, including the State of New Jersey in particular.

29. Defendants regularly file patent infringement claims against non New Jersey Corporations in New Jersey Federal Court thereby availing themselves of the benefits of New Jersey courts, laws and jurisdiction. *See AstraZeneca Pharmaceuticals LP, et al. v. Teva Pharmaceuticals*, Case 1:17-CV-02448-RMB-KMW, *filed April 10, 2017*; *See also AstraZeneca Pharmaceuticals, LP, et al. v. HBT Labs, Inc*., Case 1:17-CV-02652, *filed April 18, 2017*.

30. Defendants have obtained a Certificate of Registration with the New Jersey Department of Health Drug and Medical Devices, Registration No. 5003966; 5003887.

31. Defendants maintain a registered agent in Trenton, New Jersey.

32. Defendants, by and through their actions stated above, have consented to jurisdiction in state of New Jersey.

33. Defendants, by and through their actions stated above, are judicially estopped from challenging jurisdiction in New Jersey State and Federal Courts under the doctrine of Judicial Estoppel.

34. Defendants named herein are conclusively presumed to have been doing business in this state and are subject to New Jersey long arm jurisdiction.

## GENERAL FACTUAL ALLEGATIONS

### A. Proton Pump Inhibitors Generally

35. Proton pump inhibitors ("PPIs") are one of the most commonly prescribed medications in the United States. In 2013, more than 15 million Americans used prescription PPIs, costing more than $10 billion.

36. PPIs are indicated for the treatment of conditions such as: Gastroesophageal reflux disease ("GERD"); dyspepsia; acid peptic disease; Zollinger-Ellison syndrome; acid reflux; and peptic or stomach ulcers.

37. Nexium (esomeprazole magnesium) is a PPI that work by inhibiting the secretion of stomach acid. It shuts down acid production of the active acid pumps in the stomach thereby reducing hydrochloric acid in the stomach. The drug binds with the proton pump which inhibits the ability of the gastric parietal cell to secrete gastric acid.

38. Defendants sold Nexium with National Drug Code ("NDC") numbers 0186-5020, 0186-5022, 0186-5040, 0186-5042, 0186-40100186-4020, and 0186-4040.

39. Nexium is AstraZeneca's largest-selling drug, and in the world market, the third largest selling drug overall. In 2005, AstraZeneca's sales of Nexium exceeded $5.7 billion. In 2008, Nexium sales exceeded $5.2 billion.

**B. Dangers Associated with PPIs**

40. During the period in which Nexium has been sold in the United States, hundreds of reports of injury have been submitted to the FDA regarding the ingestion of Nexium and other PPIs. Defendants have had notice of serious adverse health outcomes through case reports, clinical studies and post-market surveillance. Specifically, Defendants have received numerous case reports of several types of kidney injuries in patients who ingested Nexium, including: Acute Interstitial Nephritis ("AIN"); Chronic Kidney Disease ("CKD"); Renal/Kidney Failure; and Acute Kidney Injury ("AKI").

41. These reports put Defendants on notice of the excessive risk of kidney injury related to the use of Nexium. However, Defendants took no action to inform Plaintiff or Plaintiff's physicians of these risks. Instead, Defendants continued to represent that Nexium did not pose any risk of kidney injuries.

**C. Acute Interstitial Nephritis Dangers Associated with PPIs**

42. Acute Interstitial Nephritis ("AIN") is the inflammation of the tubes and tissues of the kidneys. The most common symptoms of AIN are fatigue, nausea and weakness. Symptoms related to AIN can begin as soon as one week following PPI ingestion.

43. The risk of AIN among PPI users was first raised in 1992. Five years later, an additional study raised concerns. Between 2004 and 2007, at least three additional studies confirmed AIN related to PPI usage. More recent studies indicate that those using PPIs such as Nexium are at a three times greater risk than the general population to suffer AIN.

44. By July 2011, the World Health Organization adverse drug reaction report included nearly 500 cases of AIN already reported that year.

45. On or about October 30, 2014, the FDA notified Defendants that it had determined that PPIs, including Nexium, pose additional risks not previously disclosed.

46. On December 19, 2014, labeling for PPIs was updated to include a warning about AIN. The new label added, for the first time, a section about AIN that read, in relevant part, that AIN "may occur at any point during PPI therapy."

47. However, the current warning regarding the risk of AIN is far from adequate, lacking the necessary force and specificity to give patients and their healthcare providers the proper information needed to make an informed decision about whether to start or continue a drug regimen with the potential for such dire consequences. If left untreated, AIN can lead to Chronic Kidney Disease, Renal Failure, Dialysis, Kidney Transplant and/or death.

**D. Chronic Kidney Disease Associated with PPIs**

48. Chronic Kidney Disease ("CKD") is the gradual loss of kidney function. Kidneys filter waste and excess fluid from the blood, which are then excreted. When CKD reaches an advanced stage, dangerous levels of fluid, electrolytes and waste can build up in the body.

49. In the early stages of CKD, patients may have few signs or symptoms. CKD may not become apparent until kidney function is significantly impaired.

50. Treatment for CKD focuses on slowing the progression of kidney damage, usually by attempting to control the underlying cause. CKD can progress to end-stage kidney failure, which can be fatal absent artificial filtering, dialysis or a kidney transplant. Early treatment is often the key to avoiding the most negative outcomes.

51. CKD is associated with a substantially increased risk of death and cardiovascular events.

52. Studies have shown the long term use of PPIs was independently associated with a 20% to 50% higher risk of CKD, after adjusting for several potential confounding variables, including demographics, socioeconomic status, clinical measurements, prevalent co-morbidities, and concomitant use of medications.

53. In at least one study, the use of PPIs for ***any*** period of time, was shown to increase the risk of CKD by 10%.

54. Currently, the Nexium product labeling does not contain any warning regarding the increased risk of CKD.

**E. Acute Kidney Injury Dangers Associated with PPIs**

55. Studies indicate that those using PPIs such as Nexium are at a more than 2.5 times greater risk than the general population to suffer Acute Kidney Injury ("AKI").

56. Studies also indicated that those who develop AIN are at a significant risk of AKI even though they may not obviously exhibit kidney dysfunction.

57. Currently, the Nexium product labeling does not contain any warning regarding the increased risk of AKI.

**F. Safer Alternatives to PPIs**

58. Despite the fact that Nexium and other PPIs lead to an increased risk of numerous injuries as outlined herein, several safer alternatives are available, including but not limited to:

a. The use of over-the-counter calcium carbonate remedies tablets that have been available since the 1930s, such as Maalox and Tums; and/or

b. The use of histamine H2-receptor antagonists (also known as H2 blockers) that were developed in the late 1960s. H2 blockers act to prevent the production of stomach acid and work more quickly than PPIs and are prescribed for the same indications as PPI's. Examples of H2 blockers include Zantac, Pepcid and Tagamet. H2 receptor antagonists are not associated with an increased risk of renal injuries.

**G. Allegations Common to All Causes of Action**

59. Defendants knew or should have known about the correlation between the use of Nexium and the significantly increased risks of AIN, CKD, AKI and other renal impairment. Yet, Defendants failed to adequately warn of these risks from ingestion of Nexium, including the negative effects on the kidney.

60. In omitting, concealing, and inadequately providing critical safety information regarding the use of Nexium to Plaintiff and Plaintiff's healthcare providers, Defendants engaged in, and continue to engage in, conduct likely to mislead consumers, including Plaintiffs and Plaintiff's healthcare providers. This conduct is fraudulent, unfair and unlawful.

61. Despite clear knowledge that Nexium causes a significantly increased risk of CKD, AKI and other renal impairment, Defendants continue to market and sell Nexium without warning consumers or healthcare providers of the significant risks to the kidney.

### H. Plaintiff's Use of Nexium and Resulting Harm

62. Plaintiff, BillyJoe Carroll, is and was, at all relevant times, a citizen of the State of Alabama.

63. Plaintiff was born on June 19, 1951.

64. Upon information and belief, Plaintiff was prescribed Nexium sporadically from 2011 to 2016. Plaintiff ingested Nexium as prescribed by his prescribing physicians.

65. Plaintiff would not have used Nexium had he been properly warned of the kidney risks associated with its ingestion.

66. As a result of using Defendants' Nexium, Plaintiff suffers from worsening chronic kidney disease. Plaintiff sustained severe and permanent personal injuries, pain, suffering, economic loss, and emotional distress.

67. The aforementioned injuries and damages sustained by Plaintiff were caused by the ingestion of Defendants' Nexium.

## TOLLING OF THE STATUTE OF LIMITATIONS

68. Defendants negligently represented to the medical and healthcare community the FDA, to Plaintiff and the public that Nexium had been tested and was found to be safe and/or effective for its indicated use.

69. Defendants, at all relevant times, knew or should have known of the risks and defects with Nexium products, however Defendants concealed their knowledge of Nexium's risks and defects and failed to notify Plaintiff, the FDA, the public and the medical community including Plaintiff's prescribing physicians.

70. Defendants undertook such action with the intent of defrauding and deceiving the public and the medical community at large, including Plaintiff and Plaintiff's prescribing physicians, with the intent of inducing the prescription, dispensing, and/or purchasing of Nexium

for the treatment of GERD, all of which evidenced a callous, reckless, willful indifference to the health, safety and welfare of Plaintiffs herein.

71. Any applicable statute of limitations has therefore been tolled by Defendants' knowledge, active concealment and denial of the facts alleged herein, which behavior is still ongoing.

72. Plaintiff only recently discovered that Plaintiff's injuries could have been caused by the use of Nexium.

**COUNT I**
**PRODUCT LIABILITY – DEFECTIVE DESIGN**
**(N.J.S.A. 2A:58C-1, *et seq.*)**

73. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

74. Nexium is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

75. At all times relevant hereto, Nexium was expected to reach, and did reach, consumer's in Plaintiff's home state and throughout the United States, including receipt by Plaintiff, without substantial change in the condition in which it was sold.

76. At all times relevant hereto, Nexium was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following:

a. When placed in the stream of commerce, Nexium contained unreasonably dangerous design defects and was not reasonably safe as intended to be used, subjecting Plaintiff to risks that exceeded the benefits of the subject product, including, but not limited to, permanent personal injuries including, but not limited to, developing CKD and other serious injuries and side effects;

b. When placed in the stream of commerce, Nexium was defective in design and formulation, making the use of Nexium more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat GERD and other stomach-acid-related ailments;

c. The design of Nexium existed before it left the control of Defendants;

d. Nexium was insufficiently and inadequately tested;

e. Nexium caused harmful effects that outweighed any potential utility; and

f. Nexium was not accompanied by adequate instructions and/or warnings to fully apprise consumers, including Plaintiff, of the full nature and extent of the risks and side effects associated with its use, thereby rendering Defendants liable to Plaintiff.

77. In addition, at the time the subject product left the control of Defendants, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of Plaintiff's injuries without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible – indeed they were already on the market – and would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the product's utility.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

**COUNT II**
**PRODUCT LIABILITY – FAILURE TO WARN**
**(N.J.S.A 2A:58C-1, *et seq.*)**

78. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

79. Nexium was defective and unreasonably dangerous when they left the possession of Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the subject product, including but not limited to its propensity to permanent physical injuries including, but not limited to, developing CKD and other serious injuries, side effects, and death; notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other forms of treatment for GERD and other stomach-acid-related ailments. Thus, the subject products were unreasonably dangerous because an adequate warning was not provided as required pursuant to N.J.S.A. 2A:58C-1, *et seq.*

80. The subject products manufactured and supplied by Defendants were defective due to inadequate post-marketing warnings or instructions because, after Defendants knew or should have known of the risk of serious bodily harm for the use of the subject product, Defendants failed to provide an adequate warning to consumers and/or their healthcare providers of the defects of the product, and/or alternatively failed to conform to federal and/or state requirements for labeling, warnings and instruction, or recall, while knowing that the product could cause serious injury and/or death.

81. Plaintiff was prescribed and used the subject products for its intended purpose.

82. Plaintiff could not have discovered any defect in the subject product through the exercise of reasonable care.

83. Defendants, as manufacturers and/or distributors of the subject prescription product, are held to the level of knowledge of an expert in the field.

84. Defendants, the manufacturers and/or distributors of the subject prescription product, are held to a level of knowledge of an expert in the field as the Reference Listed Drug Company and the New Drug Application Holder.

85. The warnings that were given by Defendants were not accurate, clear, and/or were ambiguous.

86. The warnings that were given by Defendants failed to properly warn physicians of the increased risks of permanent physical injuries including, but not limited to, Acute Interstitial Nephritis (AIN), Chronic Kidney Disease (CKD), Renal/Kidney Failure, Acute Kidney Injury (AKI), and Clostridium difficile.

87. Plaintiff, individually and through Plaintiff's prescribing physician, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

88. Defendants had a continuing duty to warn Plaintiff of the dangers associated with Nexium.

89. Had Plaintiff received adequate warnings regarding the risks of Nexium, Plaintiff would not have used it and/or chosen a different course of treatment.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

## COUNT III
## BREACH OF EXPRESS WARRANTY

90. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

91. Defendants expressly represented to Plaintiff, other consumers, and the medical community, that Nexium was safe and fit for its intended purposes, was of merchantable quality, did not produce any dangerous side effects, and had been adequately tested.

92. Nexium does not conform to Defendants' express representations because it is not safe, has numerous and serious side effects, and causes severe and permanent injuries, including, but not limited to, developing CKD and other serious injuries and side effects.

93. At the time of making of the express warranties, Defendants knew, or in the exercise of reasonable care should have known, of the purpose for which the subject product was to be used and warranted the same to be, in all respects, fit, safe, and effective and proper for such purpose. The subject product was unreasonably dangerous because it failed to conform to an express warranty of Defendants.

94. At the time of the making of the express warranties, Defendants knew or should have known that, in fact, said representations and warranties were false, misleading, and untrue in that the subject product was not safe and fit for its intended use and, in fact, produces serious injuries to the user.

95. At all relevant times Nexium did not perform as safely as an ordinary consumer would expect, when used as intended or in a reasonably foreseeable manner.

96. Plaintiff, other consumers, and the medical community relied upon Defendants' express warranties.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, cost herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

**COUNT IV**
**PUNITIVE DAMAGES ALLEGATIONS**
**(N.J.S.A. 2A:58C-5c)**

97. Plaintiff incorporates by reference the preceding paragraphs as if fully set forth herein.

98. Despite the holding of *McDarby v. Merck & Co.*, 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008), numerous courts around the country, and in this District specifically, have found that punitive damages are appropriate under N.J. Stat. Ann. § 2A:58C-5c subsequent to *Wyeth v. Levine*, 555 U.S. 555 (2009). *See, e.g., Sullivan v. Novartis Pharms. Corp.*, 602 F. Supp. 2d 527, 534 n.8 (D.N.J. 2009) ("The validity of *McDarby* was subsequently cast into some doubt by the Supreme Court's decision in *Wyeth*.").

99. The wrongs done by Defendants were aggravated by malice, fraud, and grossly negligent disregard for the rights of others, the public, and Plaintiff, in that Defendants' conduct was specifically intended to cause substantial injury to Plaintiff. When viewed objectively from Defendants' standpoint at the time of the conduct, considering the probability and magnitude of the potential harm to others, Defendants' conduct involved an extreme degree of risk. Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with complete indifference to or a conscious disregard for the rights, safety, or welfare of others. Moreover, Defendants made material representations that were false, with actual knowledge of

or reckless disregard for their falsity, with the intent that the representations be acted on by Plaintiff and his healthcare providers.

100. Plaintiff relied on Defendant's representations and suffered injuries as a proximate result of this reliance.

101. Plaintiff therefore asserts claims for exemplary damages.

102. Plaintiff also alleges that the acts and omissions of Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiffs.

103. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, and malicious acts, omissions, and conduct, and Defendants' reckless disregard for the public safety and welfare. Defendants intentionally and fraudulently misrepresented facts and information to both the medical community and the general public, including Plaintiff, by making intentionally false and fraudulent misrepresentations about the safety of Nexium. Defendants intentionally concealed the true facts and information regarding the serious risks of harm associated with the ingestion of Nexium, and intentionally downplayed the type, nature, and extent of the adverse side effects of ingesting Nexium, despite their knowledge and awareness of these serious side effects and risks.

104. Defendants had knowledge of, and were in possession of evidence demonstrating that Nexium caused serious side effects. Notwithstanding Defendants' knowledge, Defendants continued to market the drug by providing false and misleading information with regard to the product's safety to regulatory agencies, the medical community, and consumers of Nexium.

105. Although Defendants knew or recklessly disregarded the fact that Nexium causes debilitating and potentially lethal side effects, Defendants continued to market, promote, and

distribute Nexium to consumers, including Plaintiff, without disclosing these side effects when there were safer alternative methods for treating GERD.

106. Defendants failed to provide adequate warnings that would have dissuaded healthcare professionals from prescribing Nexium and consumers from purchasing and ingesting Nexium, thus depriving both from weighing the true risks against the benefits of prescribing, purchasing, or consuming Nexium.

107. Defendants knew of Nexium's defective natures as set forth herein, but continued to design, manufacture, market, distribute, sell, and/or promote the drug to maximize sales and profits at the expense of the health and safety of the public, including Plaintiffs, in a conscious, reckless, or negligent disregard of the foreseeable harm caused by Nexium.

108. Defendants' acts, conduct, and omissions were willful and malicious. Defendants committed these acts with knowing, conscious, and deliberate disregard for the rights, health, and safety of Plaintiff and other Nexium users and for the primary purpose of increasing Defendants' profits form the sale and distribution of Nexium. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example out of Defendants.

109. Prior to the manufacture, sale, and distribution of Nexium, Defendants knew that the drug was in a defective condition and knew that those who were prescribed the medication would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the drug presented a substantial and unreasonable risk of harm to the public, including Plaintiff. As such, Defendants unreasonably subjected consumers of Nexium to risk of injury or death.

110. Despite this knowledge, Defendants, acting through their officers, directors and managing agents, for the purposes of enhancing Defendants' profits, knowingly and deliberately

failed to remedy the known defects in Nexium and failed to adequately warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of Nexium knowing these actions would expose person to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

111. Defendants' conduct was committed with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, cost herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues contained herein be tried by a jury.

## RELIEF REQUESTED

WHEREFORE, Plaintiff prays for judgment against all Defendants and award additional relief as follows:

1. Economic and non-economic damages, special damages and general damages, including pain and suffering, in an amount to be supported by the evidence at trial;

2. For compensatory damages for the acts complained of herein in an amount to be determined by a jury;

3. For disgorgement of profits for the acts complained of herein in an amount to be determined by a jury;

4. Punitive damages for the acts complained of herein in an amount to be determined by a jury;

5. For an award of attorneys' fees and costs;

6. For prejudgment interest;

7. For the costs of suit;

8. For post-judgment interest; and

9. For such other and further relief as this Court may deem just and proper.

## JURY TRIAL DEMAND

Plaintiff demands a jury as to all claims and issues triable of right by a jury.

Respectfully submitted,

/s/ Tracy A. Finken
Tracy A. Finken, Esquire
Sol H. Weiss, Esquire
ANAPOL WEISS
1040 Kings Highway North, Suite 304
Cherry Hill, New Jersey 08034
215-735-1130 (P)
215-875-7701 (F)
tfinken@anapolweiss.com
sweiss@anapolweiss.com

*/s/ Joseph J. Zonies*
Joseph J. Zonies (*pro hac vice* to be filed)
ZONIES LAW LLC
1900 Wazee Street, Ste. 203
Denver, CO 80202
T: (720) 464-5300
F: (720) 961-9252
jzonies@zonieslaw.com

***Attorneys for Plaintiff***

Dated: May 5, 2017